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Attorney Docket No. 107223.187US5



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellants: Anand R. BAICHWAL, et al.
Serial Number: 10/047,060
Filed: January 14, 2002
Entitled: **CONTROLLED RELEASE
INSUFFLATION CARRIER FOR
MEDICAMENTS**
Examiner: Carlos A. AZPURU
(Art Unit: 1615)

CERTIFICATION UNDER 37 C.F.R. § 1.10

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APPELLANTS' REPLY BRIEF UNDER 37 C.F.R. §§ 41.41 AND 41.43(b)

Sir:

Appellants submit this Reply Brief in response to the Supplemental Examiner's Answer mailed on October 6, 2004.

I. Introduction

Appellants claim a device for delivering to a patient a cohesive composite of a medicament and a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum of a specified particle size. Appellants' claims 26-43 stand rejected under 35 U.S.C. § 112, second paragraph, and 35 U.S.C. § 102(b).

In maintaining these rejections, the Supplemental Examiner's Answer again improperly fails to acknowledge that novel pharmaceutical composition limitations form an integral part of

the claimed invention. The rejection under § 112, second paragraph, rests on an unfounded objection to Appellants' defining the claimed invention using both device and composition limitations. The rejection under § 102(b) improperly assumes that references teaching the device limitations but not the composition limitations can anticipate Appellants' claims. Appellants respectfully submit that these rejections are clearly improper and should be reversed.

II. Rejection Under 35 U.S.C. § 112, second paragraph

The Examiner asserts that claims 26-43 are indefinite because they lack device limitations that define the claimed invention over the prior art. *See, e.g.*, Supplemental Examiner's Answer, page 3, lines 1-20. However, the Examiner has not identified any proper basis for rejecting the claims under 35 U.S.C. § 112, second paragraph. The Examiner has agreed that the claims are not unclear, and merely maintains that Appellants cannot properly define the claimed invention using composition limitations. *See, e.g.*, Examiner's Answer, page 3, lines 13-19; Supplemental Examiner's Answer, page 3, lines 1-7.

On the contrary, Appellants are free to define their invention as they choose, including employing claim language that combines a device and a novel composition contained within the device. The Examiner's queries regarding whether the device limitations are specific to Appellants' composition, and whether the composition could be contained in another device, are irrelevant. *See* Supplemental Examiner's Answer, page 3, lines 7-17.

The proper inquiry under § 112, second paragraph, is simply whether the claims are definite, *i.e.*, particularly point out and distinctly claim the subject matter Appellants regard as their invention. Appellants' claims meet this standard.¹

Claims 26-42 clearly describe novel cohesive composite particles that are contained in a delivery device having an output port, a chamber, and an actuator.

Claim 43 clearly describes a medicament delivery device containing a novel cohesive composite, and a mechanism for delivering the composite. The delivery mechanism is described as a "means for delivering the cohesive composite to a nasal or oral orifice," thus properly invoking interpretation under 35 U.S.C. § 112, sixth paragraph. Appellants' specification

¹ Appellants maintain that the claims of Group I, claims 26-42, are separately patentable from Group II, claim 43, for purposes of the indefiniteness rejection under § 112, second paragraph, because the claims of Group I recite the claimed device limitations, while claim 43 uses "means for" language to invoke interpretation under § 112, sixth paragraph. The claims of each group stand or fall together.

properly provides the corresponding structure required under § 112, sixth paragraph, describing in detail a number of devices suitable for performing the claimed delivery function.

Thus, claims 26-42 and claim 43 are all clear and definite, and Appellants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph, be reversed.

III. Rejection Under 35 U.S.C. § 102(b)

The Examiner maintains that claims 26-43 are anticipated by references teaching “each and every limitation of the device claim,” namely, an actuator, a chamber, and an output port. *See* Supplemental Examiner’s Answer, page 3, line 21 – page 4, line 1. The Examiner again fails to acknowledge that the cited references cannot be anticipatory because they do not teach the composition limitations of Appellants’ claims.

A proper anticipation rejection requires that the cited reference disclose each and every limitation of a claim. *See, e.g., Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 58 U.S.P.Q.2d 1508, 1512 (Fed. Cir. 2001). Appellants’ claims 26-43 cannot be anticipated by the cited references, which do not teach, and have never been asserted to teach, a cohesive composite of a medicament and a pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum of a specified particle size as claimed. Without any supporting legal authority, the Examiner has chosen to limit the anticipation analysis to the device limitations of Appellants’ claims, and wholly ignore the claimed composition limitations. However, the composition limitations must be considered as part of the claimed invention, and cannot be disregarded in making a prior art rejection. A reference must teach both the composition limitations and the device limitations to anticipate Appellants’ claims.

The Examiner has acknowledged the novelty of Appellants’ composition. *See* Final Office Action of February 26, 2003, page 8, lines 3-4. Therefore, claims 26-43 reciting a delivery device containing the novel composition simply cannot be anticipated by the cited art. The Examiner’s statements regarding the absence of claim limitations indicating that Appellants’ composition can only be held in the recited device, or that the recited device is limited in purpose to Appellants’ composition, are irrelevant. *See* Supplemental Examiner’s Answer, page 4, lines 2-10.

A single novel feature added to a known combination is patentable, and novelty can be conferred on a prior art device by a claim element that is not part of the device itself. *See, e.g., In re Bernhart*, 417 F.2d. 1395, 1398 (C.C.P.A. 1969). Indeed, “[i]f the prior art does not show

or suggest the improved element itself, it defies logical reasoning to say that the same prior art suggests the use of that improved element in a combination.” *Id.* at 1402 (emphasis added). Accordingly, many issued U.S. patents include claims reciting a prior art device containing a novel composition. *See, e.g.*, U.S. Patent Nos. 5,597,582 and 6,030,642 (claiming novel pharmaceutical formulations contained in prior art gelatin capsules). Similarly, Appellants’ claims are novel because they include novel composition limitations, even if those limitations do not represent an improvement to the device itself.

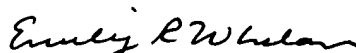
Thus, Appellants respectfully submit that the rejection of claims 26-43 under 35 U.S.C. § 102(b) is improper and should be reversed.

IV. Conclusion

For the reasons advanced above, Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the outstanding rejections, remand the application to the Examiner, and direct the Examiner to issue a Notice of Allowance.

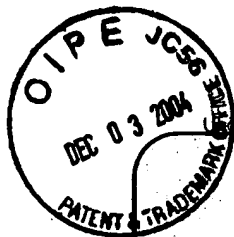
No fees are believed to be due in connection with the filing of this Reply Brief. However, please charge any payments due or credit any overpayments to our Deposit Account No. 08-0219.

Respectfully Submitted,


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Dated: 12/3/04

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